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Optimal keratoplasty for the correction of presbyopia and hypermetropia

Submission date	Recruitment status	[_] Prospectively registered
04/03/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/03/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/02/2022	Eye Diseases	

Plain English summary of protocol

Background and study aims
Presbyopia is a condition associated with aging of the eye that leads to s progressively worsening ability to focus clearly on close objects. In a younger person, the lens is soft and flexible so it can easily reshape the lens to focus on close and distant objects. With age, the lens becomes harder so it is unable to reshape as easily. Hyperopia, also known as farsightedness, is another forma of presbyopia which makes it difficult for people to focus on things that are close. Optimal keratoplasty is a new form of laser eye treatment to treat presbyopia. It works by remodeling the shape of the cornea (transparent layer forming the front of the eye) to help sharpen distance vision and near vision. The aim of this study is to investigate the safety and effectiveness of optimal keratoplasty in correcting hyperopia (long-sightedness) and presbyopia.

Who can participate?
Adults aged 40 years and over who have hyperopia and presbyopia

What does the study involve?
All participants receive optimal keratoplasty, which involves having a special laser applied to their eyes while they are lying down. The procedure takes around 10-15 minutes altogether. Before the procedure and then one hour, one day, one week and one, three and six months after the procedure, participants have an eye test in order to find out if there has been any improvement to their vision.

What are the possible benefits and risks of participating?
Participants may benefit from an improvement to their eyesight. There is a small risk that some participants may experience minor vision problems for a short time after the procedure, such as glare (light entering the eye and interfering with vision) and halos (bright circles that surround a light source).

Where is the study run from?
Istituto Europeo di Microchirurgia Oculare (Italy)

When is the study starting and how long is it expected to run for?
June 2014 to June 2016

Who is funding the study?
Istituto Europeo di Microchirurgia Oculare (Italy)

Who is the main contact?
Professor Paolo Lanzetta

Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
I-2014A27

Study information

Scientific Title
In patients with presbyopia and hypermetropia, do optimal keratoplasty improve near and distance visual acuity?

Study objectives
Optimal keratoplasty is safe and effective for the correction of hyperopia and presbyopia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Istituto Europeo di Microchirurgia Oculare (IEMO) Institutional Review Board, 22/03/2014, ref: I-2014A27

Study design
Single-centre single-arm non-randomised study

Primary study design

Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Presbyopia and hypermetropia

Interventions
All patients undergo laser irradiation of the corneal tissue using the NTK Optimal Keratoplasty (Opti-K) System.

While the patient is lying in a supine position, an output beam is directed onto the cornea in a symmetrical square ring pattern (6 and 7.2 mm diameter), so that the corneal epithelium is protected from thermal damage with a sapphire application window/suction ring. Thereafter, laser is applied at 1.93 µm wavelength. The laser is typically operated with a total delivered power of 0.80-1.28 W for a period of 150 ms. The duration of the entire procedure is approximately 10-15 minutes.

Patients are evaluated at baseline, 1 hour, 1 day, 1 week, 1 month, 3, and 6 months after treatment. The duration of a visit is about an hour. Baseline and follow-up examinations include measurement of uncorrected distance visual acuity (UDVA), uncorrected near visual acuity (UNVA), CDVA, manifest refraction, corrected near visual acuity (CNVA), presbyopic add, corneal optical coherence tomography (OCT), corneal pachymetry, slit lamp examination of the anterior segment, and dilated fundus examination.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Mean uncorrected near visual acuity is measured by ETDRS charts and standardized procedures at baseline and 6 months.

Key secondary outcome(s))
Uncorrected distance visual acuity in hypemetropic/presbyopic eyes is measured by ETDRS charts and standardized procedures at baseline and 6 months.

Completion date
01/06/2016

Eligibility

Key inclusion criteria
1. Aged 40 years and over
2. Low to moderate hypermetropia (manifest refraction: sphere between +1 to +2.5 D, absolute cylinder ≤1 D) or presbyopia (with presbyopic adds between +1D to +2.75 D)
3. Documented stable refraction
4. Corrected distance visual acuity (CDVA) of 33 Early Treatment Diabetic Retinopathy Study (ETDRS) letters or better

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Nystagmus
2. Corneal diameter ≤9 mm
3. Central corneal thickness ≤500 µm
4. Dry eye disease
5. Severe blepharitis
6. Residual, recurrent or active corneal disease or abnormality

Date of first enrolment
01/07/2014

Date of final enrolment
01/05/2016

Locations

Countries of recruitment
Italy

Study participating centre
Istituto Europeo di Microchirurgia Oculare
via Fiducio 8
Udine
Italy
33100

Sponsor information

Organisation
Istituto Europeo di Microchirurgia Oculare

ROR
https://ror.org/02t9kcf24

Funder(s)

Funder type
Other

Funder Name
Istituto Europeo di Microchirurgia Oculare

Results and Publications

Individual participant data (IPD) sharing plan
Participant level data are stored as medical charts at the center. Charts are anonymised with a numeric code. Patients signed an informed consent allowing data storage.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		18/04/2017	15/02/2022	Yes	No